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EXAMINER	
LEWIS, AARON J	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 09/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/965,681	EKLUND ET AL.	
	Examiner	Art Unit	
	AARON J. LEWIS	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1,10,21,23,30-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Behbehani et al. ('713).

As to claim 1, Behbehani et al. disclose a method for the detection and treatment of disordered breathing during sleep employing an artificial neural network (25) in which data related to breathing gas flow (fig.3) are analyzed, comprising: placing a mask (1) with a tube (3) over a patient's airway (fig.1), the mask being in communication with a source of pressurized breathing gas (7) controlled by a continuous positive airway pressure system (col.3, lines 20-21), thereby establishing a respiratory circuit; periodically sampling the gas flow in the circuit (col.3, lines 32-43 and col.4, lines 50-61); periodically calculating values for one or several parameters distinctive of various breathing patterns (col.3, lines 32-43 and col.4, lines 50-61); periodically feeding said parameter values in the neural network (col.4, lines 50-61); controlling pressurized breathing gas supply in response to the output from said neural network (col.2, lines 37-39 and col.3, lines 27-31).

As to claim 10, Behbehani et al. disclose the neural network as having a plurality of nodes (col.4, lines 35-43).

As to claim 21, Behbehani et al. disclose an apparatus for the detection and treatment of disordered breathing during sleep for use with a CPAP, the apparatus including a probe (11,15) for sampling breathing air flow data, in particular on inhalation, and an artificial neural network (25) for analyzing, directly or indirectly, said data to control breathing air pressure (col.3, lines 27-31).

As to claim 23, Behbehani et al. disclose an automatic continuous positive airways pressure apparatus comprising a probe (11,15) for sampling breathing air flow data and an artificial neural network (25) for analyzing, directly or indirectly, said data to control breathing air pressure (col.3, lines 27-31).

As to claim 30, Behbehani et al. as discussed above also disclose obtaining a frequency spectrum from the measured respiration-related variables, the frequency spectrum including at least one frequency component (col.4, lines 6-10); inputting the frequency component of the frequency spectrum into an artificial neural network trained to recognize patterns characteristic of sleep disorder breathing (col.4, lines 6-10 and col.5, lines 1-18).

As to claim 31, Behbehani et al. in obtaining a frequency spectrum perform a fast Fourier transform on a selected group of sample of measured respiration-related variables (col.3, lines 54-56).

As to claim 32, Behbehani et al. (col.5, line 47-col.6, line 23) disclose the additional step of comparing a number of outputs of the artificial neural network over a selected interval to a selected threshold value and indicating sleep disorder breathing only if the

number of outputs of the artificial neural network indicative of sleep disorder breathing exceeds the selected value.

As to claim 33, Behbehani et al. disclose normalizing the components of the frequency spectrum prior to inputting them into the artificial neural network (col.4, lines 6-10).

As to claim 34, Behbehani et al. disclose the respiration-related variable is the pressure in the interface (col.3, lines 32-43 and col.6, lines 2-6).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 2,3,5-8,12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Behbehani et al. ('713).

As to claims 2 and 3, while Behbehani et al. do not specify the particular rate at which data is fed into the neural network, the particular data feeding rate can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular data feeding rate including 2-30Hz. Given that Behbehani et al. disclose a data sampling rate of 512 Hz (col.4, line 52), one of ordinary skill would recognize that the rate at which data are actually fed into the neural network may be varied to correspond to a rate which is consistent with a number of patient breaths or partial breaths.

As to claims 5-8, official notice is taken that neural networks which are intended for use as controllers of medical devices are typically "trained" using as large a number of patients as possible and under the conditions in which the patients are intended to be treated (e.g. sleeping) in an effort to provide as large a data base of information as possible.

As to claims 12 and 13, Behbehani et al. disclose a computer (155) and storage data file. While Behbehani etal. do not expressly disclose the memory (storage data file) as being non-volatile, it would have been obvious to employ a non-volatile memory because it would have prevented the loss of any stored data during a power outage or during periods when the device is shut down.

As to claim 14, the stored data in Behbehani et al. which is obtained from training the neural network would typically include data which define apneic conditions as well as normal conditions. The data which define an apneic condition would typically include data which covers all portions of the event from its intial stages through any recovery.

As to claims 15 and 16, Behbehani et al. (col.3, lines 27-31) disclose increasing the amount of air provided to a patient responsive to a detected and analyzed "closed trajectory characteristic of the breathing pattern of the patient" being passed through the neural network and being found to be indicative of a disorder (e.g. apnea); and Behbehani et al. disclose decreasing the amount of air provided to a patient responsive to a detected and analyzed "closed trajectory characteristic of the breathing pattern of the patient" being passed through the neural network and being found to be indicative of the restoration of "normal" breathing.

5. Claims 4,11,17,18,22,24-29,35-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Behbehani et al. ('713) in view of Lin et al. ('466).

The difference between Behbehani et al. and claim 4 is the parameters comprising cepstrum coefficients.

Lin et al.(col.3, lines 46-col.4, line 62), in a kohonen neural network, teach the generation of and input of cepstrum coefficients into the neural network. These cepstrum coefficients are generated for the purpose of arranging the sampled data into matrix form to make it easier to compare (i.e. map) sampled data against stored (i.e. trained) information.

It would have been obvious to modify the neural network of Behbehani et al. to employ any well known type of neural network including a kohonen neural network as taught by Lin et al. because it would have constituted the mere substitution of one type of neural network for another.

As to claims 11, 22 and 24, Behbehani et al. as modified by Lin et al. teach a neural network which employs a kohonen map neural network.

As to claims 17 and 18, Behbehani et al. as modified by Lin et al. teach the use of linear predictive coding to analyze the parameter values fed to the neural network (col.3, lines 61-64 of Lin et al.) and the so-called A-parameters from the analysis are converted to cepstrum parameters for optimal correlation between parameter distance and conceptual distance (col.4, lines 54-62).

As to claim 25, Behbehani et al. as modified by Lin et al. teach a method of treating sleep disorder breathing, the prior art combination also including the step of inputting

cepstrum data from the respiration-related variables into an artificial neural network trained to recognize patterns of characterizing sleep disorder breathing (col.3, lines 46-col.4, line 62 of Lin et al.).

As to claim 26, Behbehani et al. (col.3, lines 54-56) disclose the additional step of obtaining a frequency spectrum from the measured respiration-related variables.

As to claim 27, Behbehani et al. (col.5, line 47-col.6, line 23) disclose the additional step of comparing a number of outputs of the artificial neural network over a selected interval to a selected threshold value and indicating sleep disorder breathing only if the number of outputs of the artificial neural network indicative of sleep disorder breathing exceeds the selected value.

As to claim 28, Behbehani et al. disclose the step of normalizing the measured respiration-related variable prior to inputting them into the artificial neural network (col.5, lines 13-18).

As to claim 29, Behbehani et al. disclose the respiration-related variable is the pressure in the interface (col.3, lines 32-43 and col.6, lines 2-6).

As to claim 35, Behbehani et al. as modified by Lin et al. as discussed above also teach the step of inputting cepstrum data from the respiration-related variables into an artificial neural network trained to recognize patterns of characterizing sleep disorder breathing (col.3, lines 46-col.4, line 62 of Lin et al.) and teach the step of comparing a number of outputs of the artificial neural network over a selected interval to a selected threshold value and indicating sleep disorder breathing only if the number of outputs of

the artificial neural network indicative of sleep disorder breathing exceeds the selected value (col.5, line 47-col.6, line 23 of Behbehani et al.).

As to claim 36, Behbehani et al. (col.3, lines 54-56) disclose the additional step of obtaining a frequency spectrum from the measured respiration-related variables.

As to claim 37, Behbehani et al. disclose the step of normalizing the measured respiration-related variable prior to inputting them into the artificial neural network (col.5, lines 13-18).

As to claim 38, Behbehani et al. as modified by Lin et al. as discussed above also teach means for inputting cepstrum data from the respiration-related variables into an artificial neural network trained to recognize patterns characterizing sleep disorder breathing (col.3, lines 46-col.4, line 62 of Lin et al.).

As to claim 39, Behbehani et al. disclose means (col.3, lines 54-56) for obtaining a frequency spectrum from the measured respiration-related variables.

As to claim 40, Behbehani et al. (col.5, line 47-col.6, line 23) disclose means for comparing a number of outputs of the artificial neural network over a selected interval to a selected threshold value and indicating sleep disorder breathing only if the number of outputs of the artificial neural network indicative of sleep disorder breathing exceeds the selected value.

As to claim 41, Behbehani et al. disclose means for normalizing the measured respiration-related variable prior to inputting them into the artificial neural network (col.5, lines 13-18).

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Behbehani et al. ('713) in view of Pardey et al. ('846).

The difference between Behbehani et al. and claim 9 is the neural network being trained with data collected from patients by use of a polysomnography system.

Pardey et al. (col.4, line 35-col.5, line 42) teach training a kohonen neural network (fig.8) with data collected from patients by use of a polysomnography system for the purpose of using the neural network as a physiological monitor for monitoring patient's EEG during sleep.

It would have been obvious to modify the training of the neural network of Behbehani et al. to include data collected from patients by use of a polysomnography system because it would have provided a data base that included patient EEG information as taught by Pardey et al.. The addition of EEG information would have made the neural network of Behbehani et al. more effective at detecting disordered breathing during sleep because the stored EEG information would have provided reference points for apea which is caused by a patient's central nervous system.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 11,19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In each of claims 19 and 20 "...the prediction error..." and "...said prediction error..." lack antecedent basis; moreover, the scope of the terminology "prediction error" is not clear from the claim language. That is, the process which applicant employs to generate a "prediction error" is not apparent from the claim language.

9. Regarding claim11, the phrase "map like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d). One way of correcting this ambiguity is to rephrase the above expression as –kohonen map ANN--.

Claim Objections

10. Claim 38 is objected to because of the following informalities: in line 3, "...interfac e..." should read –interface--. Appropriate correction is required.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant artificial neural networks.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (703) 308-0716. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, WEILUN LO can be reached on (703) 308-1957. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AARON J. LEWIS
Primary Examiner
Art Unit 3761

Aaron J. Lewis
September 15, 2003